

# UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No. CP 107P  
First Inventor Jane Hirsh  
Title Pulsatile Release Compositions of Milnacipran  
Express Mail Label No. EL 717 746 189 US

## APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

## ADDRESS TO:

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria VA 22313-1450

1. ☒ Fee Transmittal Form (e.g., PTO/SB/17)  
(Submit an original and a duplicate for fee processing)
2. ☒ Applicant claims small entity status.  
See 37 CFR 1.27.
3. ☒ Specification [Total Pages 50]  
(preferred arrangement set forth below)
  - Descriptive title of the invention
  - Cross Reference to Related Applications
  - Statement Regarding Fed sponsored R & D
  - Reference to sequence listing, a table, or a computer program listing appendix
  - Background of the Invention
  - Brief Summary of the Invention
  - Brief Description of the Drawings (if filed)
  - Detailed Description
  - Claim(s)
  - Abstract of the Disclosure
4. ☐ Drawing(s) (35 U.S.C. 113) [Total Sheets       ]
5. Oath or Declaration [Total Sheets 1]
  - a. ☐ Newly executed (original or copy)
  - b. ☐ Copy from a prior application (37 CFR 1.63(d))  
(for continuation/divisional with Box 18 completed)
  - i. ☐ **DELETION OF INVENTOR(S)**  
Signed statement attached deleting inventor(s)  
name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☒ Application Data Sheet. See 37 CFR 1.76

7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)
8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
  - a. ☐ Computer Readable Form (CRF)
  - b. Specification Sequence Listing on:
    - i. ☐ CD-ROM or CD-R (2 copies); or
    - ii. ☐ Paper
  - c. ☐ Statements verifying identity of above copies

## ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & document(s))
10. ☐ 37 CFR 3.73(b) Statement (when there is an assignee) ☐ Power of Attorney
11. ☐ English Translation Document (if applicable)
12. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations
13. ☐ Preliminary Amendment
14. ☒ Return Receipt Postcard (MPEP 503)  
(Should be specifically itemized)
15. ☐ Certified Copy of Priority Document(s)  
(if foreign priority is claimed)
16. ☐ Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. ☐ Other: .....

18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: .....

Prior application information:

Examiner

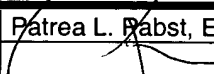
Art Unit:

For CONTINUATION OF DIVISIONAL APPS only; The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

## 19. CORRESPONDENCE ADDRESS

☒ Customer Number: 23579 OR ☐ Correspondence address below

Name	Patrea L. Pabst, Holland & Knight LLP		
Address	2000 One Atlantic Center 1201 West Peachtree Street		
City	Atlanta	State	GA
Country	United States of America	Zip Code	30309-3400
	Telephone	(404) 817-8473	Fax (404) 817-8588

Name (Print/Type)	Patrea L. Pabst, Esq.	Registration No. (Attorney/Agent)	31,284
Signature		Date	October 22, 2003

This collection of information is required by 37 CFR 1.53(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

# FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 464.00

## Complete if Known

Application Number  
Filing Date October 22, 2003  
First Named Inventor Jane Hirsh  
Examiner Name  
Art Unit  
Attorney Docket No. CP 107P

## METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit  
Account  
Number  
Deposit  
Account  
Name

50-1868

Holland & Knight LLP

The Director is authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	770	2001	385	Utility filing fee	385.00
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	
SUBTOTAL (1)					(\$ 385.00

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims		Fee from below	Fee Paid
Total Claims	24	-20** =	4	X 9.00	36.00
Independent Claims	4	-3** =	1	X 43.00	43.00
Multiple Dependent					

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$ 79.00

\*\*or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for ex parte reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ .00

## SUBMITTED BY

Name (Print/Type) Patrea L. Pabst Registration No. (Attorney/Agent) 31,284 Telephone (404) 817-8473  
Signature Date October 22, 2003

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.  
SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Jane Hirsh, Roman V. Rariy and Michael Heffernan

Serial No.: Express Mail Label No.: EL 717 746 189 US

Filed: October 22, 2003 Date of Deposit: October 22, 2003

For: *PULSATILE RELEASE COMPOSITIONS OF MILNACIPRAN*

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**EXPRESS MAIL TRANSMITTAL LETTER  
FOR PATENT APPLICATION AND CERTIFICATE OF MAILING**

Sir:

Pursuant to 35 U.S.C. § 21(a) as amended by Public Law 97-247 and 37 C.F.R. § 1.10, applicants enclose for filing the attached patent application entitled "*Pulsatile Release Compositions of Milnacipran*", which claims priority to U.S.S.N. 60/421,640 filed October 25, 2002, U.S.S.N. 60/431,626 filed December 5, 2002, U.S.S.N. 60/431,627 filed December 5, 2002, U.S.S.N. 60/431,906 filed December 9, 2002, U.S.S.N. 60/431,861 filed December 9, 2002, U.S.S.N. 60/443,618 filed January 29, 2003, U.S.S.N. 60/459,061 filed March 28, 2003, U.S.S.N. 60/458,994 filed March 28, 2003 and U.S.S.N. 60/458,995 filed March 28, 2003. The application includes 1 page of abstract, 44 pages of specification, 5 pages of claims, and an unexecuted Declaration for Patent Application. An executed Declaration for Patent Application, Assignment of rights in the application from Jane Hirsh, Roman V. Rariy, and

Michael Heffernan to Collegium Pharmaceutical, Inc., Power of Attorney or Authorization of Agent, and a Statement Under 37 C.F.R. § 3.73(b) will be submitted shortly.

Commissioner is authorized to charge the amount of \$464.00 to Deposit Order Account No. 50-1868 to cover the filing fee for small entity. It is believed that this is the proper filing fee for a small entity as the application contains 4 independent claims, and a total of 24 claims.

This application is entitled to claim small entity status under 37 C.F.R. § 1.27.

This application is being filed on October 22, 2003 by mailing the application to Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 via the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10. The Express Mail label number appears in the heading of this paper which is attached to the application papers pursuant to 37 C.F.R. § 1.10(b).

The Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment in connection with this application, to Deposit Order Account No. 50-1868. To facilitate this process, applicants have enclosed a duplicate of this transmittal.

Title: Pulsatile Release Compositions of Milnacipran  
Filed: October 22, 2003  
Express Mail Transmittal Letter for  
Patent Application and Certificate of Mailing  
Express Mail Label No.: EL 717 746 189 US  
Date of Deposit: October 22, 2003

All correspondence concerning this application should be mailed to:

**Customer No. 23579**  
**Patrea L. Pabst, Esq.**  
**HOLLAND & KNIGHT LLP**  
**Suite 2000, One Atlantic Center**  
**1201 West Peachtree Street, N.E.**  
**Atlanta, Georgia 30309-3400**

**(404) 817-8473 (Telephone)**  
**(404) 817-8588 (Fax)**

Respectfully submitted,



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Patrea L. Pabst  
Reg. No. 31,284

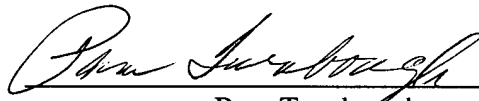
Date: October 22, 2003

**HOLLAND & KNIGHT LLP**  
**Suite 2000, One Atlantic Center**  
**1201 West Peachtree Street, N.E.**  
**Atlanta, Georgia 30309-3400**  
**(404) 817-8473 (Telephone)**  
**(404) 817-8588 (Fax)**

Title: Pulsatile Release Compositions of Milnacipran  
Filed: October 22, 2003  
Express Mail Transmittal Letter for  
Patent Application and Certificate of Mailing  
Express Mail Label No.: EL 717 746 189 US  
Date of Deposit: October 22, 2003

**CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10**

I hereby certify that this Express Mail Transmittal Letter for Patent Application and Certificate of Mailing and any documents referred to as attached therein are being deposited with the United States Postal Service on this date, October 22, 2003, in an envelope as "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10, Express Mail Label No. EL 717746189 US, addressed to Mail Stop Patent Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
Pam Turnbough

Date: October 22, 2003

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